



## (11)(21) PI 9202079 A

(22) Data de Depósito: 29/05/92

(43) Data de Publicação: 14/12/93 (RPI 1202)

REPÚBLICA FEDERATIVA DO BRASIL Ministério da Indústria, do Comércio e do Turismo Instituto Nacional da Propriedade Industrial

(54) Título: Implante por cateterismo de uma prótese arterial

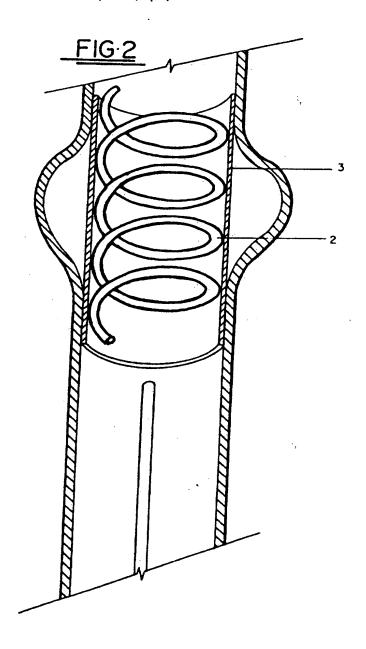
(71) Depositante(s): Hector Américo Berone (BR/SP)

(72) Inventor(es): Hector Américo Barone

(74) Procurador: Sul América Marcas e Patentes S/C Ltda

(57) Resumo: "implante por catetarismo de uma prótese arterial", constituído por um dispositivo (1) confeccionado por uma liga metálica de titânio e níquel, conhecida como "nitinol", sob uma temperatura entre 36" e 41" C, em forma de arame espiralado, o qual,

para ser introduzido em artérias lesionadas por aneurismas, é posteriormente restriado para adquirir o formato retilíneo, sendo que, quando introduzido, por cateterismo, em conjunto com o tubo (2) introdutor e enxerto (3), ou prótese flexível, o mesmo, so entrar em contato com a temperatura interna do paciente, entre 30° e 41°C, toma a forma oroginal espiralada, pressionando o enxerto (3) contra as paredes das artérias tomando uma prótese arterial definitiva; numa opção construtiva, o arame é revestido por um tubo de plástico ou tecido (5), de maneira que, quando da expansão para a formação do arame espiralado, configura-se uma "mola encapada", que é a própria prótese; em outra opção construtiva, um "Stent" (7) em material despregável é inserido entre o arame e a prótese (8), conformando um corpo cilindrico quando da expansão por temperatura que-fica pressionado entre o arame espiralado (6) e a mencionada prótese (8), evitando atrito entre as mesmas.



\*2

(11) (21) PI 9202#079 A

(22) Filing Date: May 29, 1992

(43) Publishing Date: December 14, 1993 (Official Gazette RPI 1202)

(54) Title: Catheterism implantation of an arterial prosthesis

(72) Inventor: Hector Américo Barone

"Catheterism implantation of an arterial prosthesis"

## \$pccification

Present application relates to an innovative device made from metal alloy of Titanium and Nickel, known as "nitinol", for the reinforcement of aneurysm injured arterial walls, which specific characteristics allow a perfect yield for its proposals.

A novel metal alloy was recently discovered, the "nitinol" that came from an effort to make a Titanium metal alloy less fragile, wherein Nickel was added.

It was noted that such alloy was able to "memorise" a determined shape at a given temperature. With this alloy there were already built several mechanisms that return to their original shape, when submitted to the same temperature that they were made.

In the medical-surgical field, specifically in the arterial prosthesis, synthetic cloth arterial prosthesis are widely known, that can be introduced through intraluminal way, by surgery or Catheterism, with "balloon" like catheters, which, in final analysis limits the diameter of the targeted artery.

Bearing in mind this inconvenience and interested in providing improvements to the sector of medicine dedicated to the implant of arterial prosthesis, the Inventor, after several researches, has created and developed this "Catheterism implantation of an arterial prosthesis", that relates to a device made from a metal alloy based in Titanium and Nickel, the "nitinal", formed by a spiral wire which conformation is executed within 36 and 41 Celsius degrees, that corresponds to an acceptable range in terms of the normal temperature of the human body, said wire being cooled, making it straight for its insertion, through a catheter or not, to the damaged artery of the human being, for the compression of a polyester flexible graft, or others, to the arterial walls.

The artery compression is made by the device that, when in contact with the interior temperature of the patient, that should vary between 36 to 41°C, becomes spiralled, moulding the graft that reinforces the arterial walls, not needing to be withdrawn after the compression since, due to its configuration, it allows the free flow of the blood, causing no inconvenience to the patient.

In another improved embodiment option the invention basically comprises a device formed by a wire made from "nitinol", and by these means with the so called molecular thermomemory said wire coated by a tubular plastic or cloth coating which external diameter could vary within predetermined parameters while its minimum diameter, or internal, is projected to cover said prosthesis making cloth. Therefore, the wire upon returning to its original conformation due to the temperature, becomes a "coated spring", where the prosthesis itself is conformed. With this embodiment the use of special catheters, such as "balloon like" amongst others, is suppressed.

Another embodiment relates to the possibility of the "spiralled wire" formation by the expansion due to the raise in temperature when in contact with the blood stream, that acts as a "Stent" expander element placed between the prosthesis and said spiralled wire, avoiding an eventual friction on its cloth.

To better clarify the specification drawings are annexed, to which the following references are made:

- Fig. 1: Shows a cross sectional view of a device being introduced in a injured artery;
  - Fig. 2: Shows a cross sectional view of the already spiralled wire inside an artery;
- Fig. 3: Shows a view of a prosthesis in a second constructive version, or rather, obtained by the coated "nitinol" wire expansion;
- Fig. 4: Shows a view of a "Stent" implant configured between the spiralled wire and the prosthesis.

The "Catheter'sm implantation of an arterial prosthesis", object of this application, basically consists on a device (1) made from a metal alloy of Titanium and Nickel, the "nitinol", in a spiralled wire shape, which conformation is done between 36 to 41°C, being thereafter cooled to acquire a linear shape that, by catheterism together with the introducer tube (2) and the flexible graft (3), is introduced into the injured artery and when this device (1) is in contact with the patient's interior temperature, that should vary between 36 to 41°C, said device reacquires the original spiralled shape and pressures the flexible graft (3) that is than moulded over the artery walls, forming the arterial prosthesis.

In another embodiment, a "nitinol" wire (4), thus having molecular thermomemory, when cooled to acquire this condition is coated by a tubular plastic or cloth covering (5) that can present different external diameters while its internal diameter is projected with a minimum value to act as wire coating (4). In this version, contrary to the previous one, the wire (4) in inserted within a conveniently dimensioned covering and not within a cylindrical element of much higher diametrical dimensions. Thus, when the expansion for the formation of the spiralled wire, a "coated spiral" is configured, that is the prosthesis itself. Therefore, the graft application is facilitated.

In another embodiment, the wire when in contact with the blood stream's temperature conforms the spiralled wire (6) that, simultaneously to the expansion liberates a "detachable" material with special constitution, forming a cylindrical "Stent" (7) between the spiralled wire and the prosthesis (8), remaining fixed between them so as to avoid any eventual friction between the spiral (6) and the cloth. With the suppression of the direct friction between the spiralled wire and the prosthesis, due in its majority to the constant blood stream, the quality and durability of the prosthesis is improved.

An important factor to be noted is that in all versions the invention allows free flow of the blood stream, by no means harming the patient.

Present application thus relates to a new concept on arterial prosthesis with several embodiment options, which technical characteristics, constructive and functional, are completely different from the prior art.

Due to its truly innovative characteristics and to the advantages that it offers, filling all novelty and originality requirements of the kind, present "Catheterism

implantation of an arterial prosthesis" provides all the necessary conditions to receive the Invention Privilege.

## \$et of Claims

1) "Catheterism implantation of an arterial prosthesis", characterized by the fact that it presents a device (1) made from a metal alloy of Titanium and Nickel, the "nitinol", under temperature range of 36 to 41°C, in a spiralled wire shape, that is thereafter cooled to acquire a linear shape, in order to be introduced, by catheterism, together with a introducer tube (2) and flexible graft (3), in arteries injured by ancurysm, forming an arterial prosthesis, while the device (1) pressures the graft (3) since when in contact with the patient's internal temperature it acquires the spiralled shape and compresses the graft (3) to the arterial walls.

2) "Catheterism implantation of an arterial prosthesis" according to claim 1, characterized by the fact that in an embodiment option, a "nitinol" wire (4), thus having a molecular thermomemory, receives, when cooled to acquire a cylindrical condition, a tubular plastic or cloth covering (5), that externally can present different diameters while its internal diameter is dimensioned to act as a wire (4) coating; when the expansion to the spiral condition occurs, due to the human body's temperature,

forming a "coated spring" that is the prosthesis itself.

3) "Catheterism implantation of an arterial prosthesis" according to claim 1, characterized by the fact that in an embodiment option, the spiralled made wire, thereafter cooled to assume a cylindrical shape, receives a special material "Stent" (7), between the spiralled wire (6) and the prosthesis (8), said "Stent" having the singularity of being of the "detaching" kind during the spiralled wire (6) conformation per temperature, being pressed between this and the said prosthesis (8), avoiding direct friction.

## Abstract

"Catheterism implantation of an arterial prosthesis", constituted by a device (1) made from a metal alloy of Titanium and Nickel, known as "nitinol" under a temperature between 36 and 41°C, in a spiralled wire shape, to be introduced into aneurysm injured arteries is thereafter cooled to acquire a linear shape, while when introduced, by catheterism, together with the introducer tube (2) and graft (3), or flexible prosthesis, that when in contact with the patient's internal temperature, between 36 and 41°C, acquires the spiralled shape and compresses the graft (3) to the arterial walls thus forming the conclusive arterial prosthesis; in another embodiment option the wire is coated with a tubular plastic or cloth covering (5) so as to when the expansion to the spiral condition occurs a "coated spring" that is the prosthesis itself is formed; in another embodiment a "Stent" made from detachable material is inserted between the wire and the prosthesis (8), conforming a cylindrical body that when expanded be temperature stays pressed between the spiralled wire (6) and said prosthesis (8), avoiding friction between said parts.